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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,567	03/07/2002	Jonathan P. Wong	NEL-006	7851

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	10/091,567	WONG ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communicati n appears on the cover sh et with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to paper file 22 June 2004.

Claims 20-32 are under consideration.

Rejections Maintained

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 20-23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Sha *et al.*

Applicant argues that Xu *et al.* explain that there is a difference between complexed and encapsidated and that such teachings can be found in other references such as Bajoghli. Also, that the prior art does not mix the same amount as the instant invention and points to the specification, and that based on the specification and the Declaration, there is a difference between the Sha *et al.* and success of the instant invention, the products are different.

The arguments have been fully considered and not found persuasive.

Xu *et al.* teach about lipoplexes and the cited passage states when the ratio approaches 1:1 the transformation occurs. They refer to lipoplexes as the structure of the complex between DNA and lipid and encapsidation is part of the process as the ratio approaches 1:1. Applicant argues that their formulation is 1:25. The cited support

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is not commensurate with the ratio applicant argues because it does not teach the 1:25 ratio. Also, from the specification (page 10 lines 15-16) it is not clear how Applicant obtained 1:25 ratio. The phrase "of 400 micrograms DNA/ml of 10mg/ml" may be 1:25 if only the 400 micrograms DNA/ml part is considered but what does "of 10mg/ml" do to the concentration.

Bajoghli teaches in the rest of the sentence quoted by applicant, that "there is also some evidence that cationic liposomes do not actually encapsidate DNA". The quoted passage by Applicant requires a critical lipid density but does not state what it is. One of skill in the art could look at Xu *et al.* and estimate the value to be near 1:1 but as stated above, this is not similar to the value disclosed by applicant.

Claim 26 is included in this rejection because it is not clear that the limitation changes the product of claim 20.

The cited passages fail to show that encapsidation requires a special ratio of DNA/lipid or the ratio used by Applicant or that it is a distinct structure from complexes.

Thus, Sha *et al.* anticipate the claimed invention.

Claim Rejections - 35 USC § 103

Claims 20, 24, 25, and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sha *et al.* and Promega Catalog.

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Applicant argues that the references must teach or suggest as a whole the invention and all the limitations in the claims. Also, that the liposomal vaccine of Sha is not encapsidated.

The arguments have been fully considered and not found persuasive.

As discussed above, the cited references do not differentiate the invention from the prior art or show that the invention complexes are different.

Applicant has not pointed out what limitations are not covered.

Thus, claims 20, 24, 25, and 27-32 are unpatentable over Sha *et al.* and the Promega Catalog.

New Rejections Necessitated By amendment

Claim Rejections - 35 USC § 112

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is requested to point to the support for the limitation in the claim. In the response to the 102 rejection Applicant pointed to page 10, lines 15-16 but it is not clear because of the end of the phrase "of 10 mg/ml" can alter the value of the ratio.

Conclusion

No claim is allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

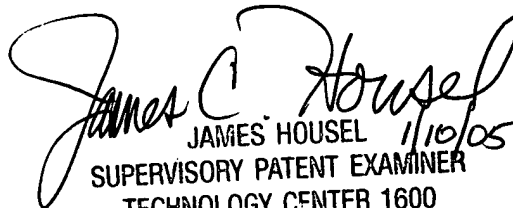
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Myron G. Hill
Patent Examiner
January 10, 2005


JAMES HOUSEL 1/10/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600